

K 955417

MAR - 8 1996

ATTACHMENT 2

510(k) Summary**VITAL PAK**

Prepared February 29, 1996

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and Sec. 807.92(c).

1. Submitter's Name and Address:

Vital Signs, Inc.
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Totowa, NJ 07512

2. Contact Person:

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3. Name of Device:

Classification Name:	Accessory to Monitor, Cardiac Output, Thermal
Common Name:	Anesthesia Kit
Proprietary Name:	Vital Pak

4. Classification:

C.F.R. Section:	21 CFR 870.1435
Panel:	Cardiovascular
Product Code:	74KFN
Device Class:	Class II

5. Performance Standards:

No performance standard(s) applicable to this device have been promulgated under Section 514 of the Food, Drug and Cosmetic Act.

6. Device Description and Indicated Use:

The Vital Pak is an expansion of the currently marketed General Anesthesia System (GAS). It is, like the GAS, a customizable, convenience packaged group of sterile and non-sterile disposable devices. The devices are used during the set-up and performance of anesthesia procedures (e.g., general anesthesia, cardiac anesthetic procedures, etc.) and may, depending on the institutions protocol, be used during the transport to and recovery from the same anesthetic procedure. The Vital Pak is designed to conveniently package together those devices, chosen by each institution, that are legally marketed, and typically and repeatedly used by the anesthesia clinicians.

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vital signs inc.

7. Substantial Equivalence:

The Vital Pak is an expansion of the General Anesthesia System (GAS). The GAS was described in the 510(k) K945455 and received FDA clearance on December 23, 1994. Since, the addition of legally marketed devices to the GAS does not either change the intended use of the kit, nor does it affect the safety or efficacy of the kit, the Vital Pak is substantially equivalent to the GAS.

The Vital Pak is "convenience packaging" of devices legally marketed and commercially available. The packaging of this convenience kit does not alter the intended use of any of its individual devices. The Vital Pak is as safe and effective as the devices included. Therefore, the Vital Pak is also substantially equivalent to the devices included in it.

[END OF SUMMARY]